

PCT



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>5</sup> :  A61B 17/00</p>	<p>A2</p>	<p>(11) International Publication Number: WO 90/14795  (43) International Publication Date: 13 December 1990 (13.12.90)</p>
<p>(21) International Application Number: PCT/US90/02657 (22) International Filing Date: 16 May 1990 (16.05.90) (30) Priority data: 352,337 16 May 1989 (16.05.89) US (71)(72) Applicant and Inventor: YOON, InBae [US/US]; 2101 Highland Ridge Drive, Phoenix, MD 21131 (US). (74) Agent: EPSTEIN, Robert, H.; Epstein, Edell &amp; Retzer, 932 Hungerford Drive, Suite 6, Rockville, MD 20850 (US).</p>		<p>(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent)*, DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), SE (European patent).  Published <i>Without international search report and to be republished upon receipt of that report.</i></p>
<p>(54) Title: SUTURE DEVICES PARTICULARLY USEFUL IN ENDOSCOPIC SURGERY</p> <p>(57) Abstract</p> <p>Suture devices, particularly useful in endoscopic surgery, include a suture device made of bioabsorbable material having an elongate body member with a sharp distal end for penetrating tissue and means for locking the suture device in tissue to prevent forward and rearward movement and a suture device made of bioabsorbable material having a hinge-like joint for folding a distal portion at a precise location to be juxtaposed with a proximal portion for adjustable locking. Methods of using the suture devices for joining tissue sections, such as in tuboplasty, for closing anatomical lumens and for subcuticular suturing.</p>		

\* See back of page

BEST AVAILABLE COPY

# DESIGNATIONS OF "DE"

Until further notice, any designation of "DE" in any international application whose international filing date is prior to October 3, 1990, shall have effect in the territory of the Federal Republic of Germany with the exception of the territory of the former German Democratic Republic.

## FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MC	Monaco
AU	Australia	FI	Finland	MG	Madagascar
BB	Barbados	FR	France	ML	Mali
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GR	Greece	NL	Netherlands
BJ	Benin	HU	Hungary	NO	Norway
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	SD	Sudan
CF	Central African Republic	KP	Democratic People's Republic of Korea	SE	Sweden
CG	Congo	KR	Republic of Korea	SN	Senegal
CH	Switzerland	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
DE	Germany, Federal Republic of	LU	Luxembourg	TG	Togo
DK	Denmark			US	United States of America

## SUTURE DEVICES PARTICULARLY USEFUL IN ENDOSCOPIC SURGERY

## BACKGROUND OF THE INVENTION

Field of the Invention

1       The present invention relates to surgical suture devices  
2       and, more particularly, to suture needle-like suture devices  
3       made of bioabsorbable materials particularly useful in  
4       endoscopic surgery and methods of suturing using such suture  
5       devices.

6

7       Discussion of the Prior Art

8       Suturing of bodily tissue is a time consuming part of most  
9       surgical procedures including both open surgery and endoscopic  
10      or closed surgery. By open surgery is meant surgery wherein  
11      the surgeon gains access to the surgical site via a relatively  
12      large incision, and by endoscopic surgery is meant surgery  
13      wherein the surgeon gains access to the surgical site via one  
14      or more portals through which endoscopes are introduced to view  
15      the surgical site and through which instruments, such as  
16      forceps, cutters, applicators and the like, are introduced to  
17      the surgical site. There are many common endoscopic surgical  
18      procedures, including arthroscopy, laparoscopy (pelviscopy),  
19      gastroentrosopy and laryngobronchoscopy, for example. In the  
20      past, suturing has been accomplished with the use of a sharp  
21      metal suture needle attached to the end of a length of suture  
22      material, the suture needle being caused to penetrate and pass  
23      through the tissue pulling the suture material through the  
24      tissue. Once the suture material has been pulled through the

SUBSTITUTE SHEET

1 tissue, the surgeon ties a knot in the suture material, the  
2 knotting procedure allowing the surgeon to adjust the tension  
3 on the suture material to accommodate the particular tissue  
4 being sutured and control approximation, occlusion, attachment  
5 or other conditions of the tissue. The ability to control  
6 tension is extremely important to the surgeon regardless of the  
7 type of surgical procedure being performed; however, knotting  
8 of the suture material is time consuming and tedious work,  
9 particularly in microsurgery and endoscopic surgery. That is,  
10 in microsurgery suturing is necessarily time consuming due to  
11 the small size of the suture needle and the suture material and  
12 the concomitant difficult manipulation required to pass the  
13 suture needle through the tissue and to tie a knot in the  
14 suture material. With respect to endoscopic surgery, suturing  
15 and tying knots represents an even more time consuming  
16 procedure due to the difficult maneuvers required.  
17 Accordingly, while endoscopic surgery would be preferred for  
18 most procedures, the advantages are often outweighed by the  
19 disadvantages caused by the length of time required to complete  
20 the endoscopic surgical procedure, which time is greatly  
21 extended due to the time required for suturing. Another  
22 disadvantage of suturing with a metal suture needle and suture  
23 material during endoscopic surgery is that the suture needle  
24 is difficult to hold and manipulate and can be easily dropped.  
25 Should the suture needle be dropped, open surgery with its

1 attendant disadvantages must be performed to find and remove  
2 the needle.

3       There have been many attempts to provide devices to take  
4 the place of conventional suturing with a suture needle and a  
5 length of suture material; however, such prior art devices have  
6 essentially been staples, clips, clamps or other fasteners not  
7 providing the adjustable tension obtained by the surgeon while  
8 knotting a length of suture material. U. S. Patents No.  
9 3,827,277 to Weston, No. 4,060,089 to Noiles, No. 4,490,326 to  
10 Beroff et al, No. 4,513,746 to Aranyi et al, No. 4,532,926 to  
11 O'Holla, No. 4,548,202 to Duncan, No. 4,573,469 to Golden, No.  
12 4,590,937 to Deniega, No. 4,595,007 to Meride, No. 4,602,634  
13 to Barkley, No. 4,646,741 to Smith, No. 4,671,280 to Dorband  
14 et al, No. 4,719,917 to Barrows et al and No. 4,741,337 to  
15 Smith et al are representative of such prior art devices for  
16 use in place of conventional suturing. Many of these prior art  
17 devices are made of bioabsorbable materials such that the  
18 devices are absorbed over time into the bodily tissue and do  
19 not have to be removed after the bodily tissue has healed.

20       There exist many compositions useful as bioabsorbable  
21 materials, as represented by the above patents and by U.S.  
22 Patents No, 3,739,773 to Schmitt et al, No. 3,797,499 to  
23 Schneider, No. 4,141,087 to Shalaby et al, No. 4,300,565, No.  
24 4,523,591 to Kaplan et al and No. 4,649,921 to Koelmel et al  
25 which discuss characteristics of various bioabsorbable

1 materials and medical devices desirably manufactured of such  
2 materials, such medical devices being of a type designed to be  
3 engaged in, embedded in or otherwise attached to various types  
4 of bodily tissue, such as bone, muscle, organs, skin and other  
5 soft tissue, to remain in place in the tissue until the device  
6 is absorbed into the body.

7 U.S. Patent No. 3,570,497 to Lemole discloses a suture  
8 device formed of a needle with a piercing point extending from  
9 a latch cord carrying notches designed to pass through a latch  
10 collar, the latch cord being resilient to be curved upon itself  
11 to form a suture stitch without requiring tying of a knot;  
12 however, the latching function does not provide the same feel  
13 and tension control as knotting a length of suture material.  
14 U.S. Patent 4,548,202 to Duncan uses similar structure in a  
15 tissue fastener device in that serrations or angled barbs are  
16 provided on spaced legs passing through tissue to be engaged  
17 by an apertured receiver or a flexible filament mesh. U.S.  
18 Patent No. 3,123,077 to Alcamo discloses a surgical suture  
19 carrying raised projections or depressions or teeth such as  
20 barbs or spicules to snag or penetrate tissue to effectively  
21 hold a sewed incision or wound.

22 Endoscopic surgery is preferred over open surgery due to  
23 the greatly reduced trauma and wound healing time for the  
24 patient and due to concomitant cost savings associated with  
25 shorter hospital stays and performing surgery without general

1 anesthesia and in non-hospital or out-patient surgery sites.  
2 Accordingly, there has been much effort spent to develop  
3 techniques for facilitating the suturing normally performed by  
4 use of a metal suture needle and a length of suture material.  
5 Alternative techniques proposed have included electrical  
6 coagulation, mechanical devices such as clips, clamps and  
7 staples, and lasers; however, no well accepted alternative has  
8 yet been found in that suturing and tying are essential and  
9 vital parts of most surgical procedures. That is, to date the  
10 proposed alternatives have had disadvantages, including  
11 increased risk to the patient, while not providing the surgeon  
12 with the advantages of suturing and tying and not being useful  
13 in a wide range of procedures to allow expansion of the areas  
14 in which endoscopic surgery can be effectively performed.  
15 Thus, there is a great need for suture devices, particularly  
16 useful in endoscopic surgery, that allow surgeons to suture and  
17 tie knots in a manner with which they are familiar without  
18 undue concern as to the loss of the suture needle and further  
19 for suture devices that allow controlled approximation of  
20 tissue and tying to produce controlled tension.

#### 21 SUMMARY OF THE INVENTION

22 Accordingly, it is a primary object of the present  
23 invention to provide suture devices particularly useful in  
24 endoscopic surgery overcoming the above mentioned disadvantages  
25 of the prior art.

1 Another primary object of the present invention is to  
2 construct a suture device having characteristics similar to a  
3 suture needle such that a surgeon can manipulate the suture  
4 device to penetrate tissue using techniques similar to those  
5 used for suturing with a suture needle and a length of suture  
6 material.

7 A further object of the present invention is to provide  
8 a suture needle-like suture device in the form of a body member  
9 made of bioabsorbable material having an enlarged proximal end,  
10 a sharp distal end and protrusions therebetween configured such  
11 that the suture device can be inserted through tissue in only  
12 a forward direction and locked in the tissue with forward  
13 movement limited by the enlarged proximal end and rearward  
14 movement limited by the protrusions which can be whisker-like  
15 filaments angled away from the sharp distal end toward the  
16 enlarged proximal end. Any portion of the distal end of the  
17 needle protruding from the tissue can be cut off and removed.

18 An additional object of the present invention is to  
19 provide a suture needle-like suture device for joining bodily  
20 tissue having a distal portion terminating at a sharp tip and  
21 a proximal portion hingedly connected with the distal portion  
22 such that the distal portion can penetrate the tissue and be  
23 folded or bent at the hinge to a position juxtaposed with the  
24 proximal portion with the sharp tip received in an opening



1 carried by the proximal portion to be adjustably locked  
2 therein.

3 Another object of the present invention is to provide a  
4 method of suturing an opening in skin by penetrating the  
5 subcutaneous fat layer with suture needle-like suture devices  
6 made of bioabsorbable material and movable only in a forward  
7 direction to approximate the opposite sides of the opening.

8 The present invention has another object in the use of a  
9 suture needle-like suture device made of bioabsorbable material  
10 and having a coiled configuration in a method of closing an  
11 anatomical lumen.

12 A further object of the present invention is to provide  
13 a suture needle-like suture device made of bioabsorbable  
14 material that can be locked in tissue to prevent both forward  
15 and rearward movement.

16 An additional object of the present invention is to  
17 position a hinge-like joint on a suture needle-like suture  
18 device made of bioabsorbable material such that a distal  
19 portion of the suture device can be folded at a precise  
20 location after penetration of tissue to be juxtaposed with a  
21 proximal portion of the suture device to facilitate use of the  
22 suture device to produce desired adjustable locking of the  
23 distal and proximal portions.

24 A further object of the present invention is to configure  
25 suture needle-like suture devices made of bioabsorbable

1 material to allow a knotting function to be produced similar  
2 to tying a knot in a length of suture material during  
3 conventional suturing.

4 The present invention is generally characterized in a  
5 suture needle-like suture device made of bioabsorbable material  
6 including an elongate body member having a sharp distal end for  
7 penetrating tissue and carrying means for locking the suture  
8 device in tissue to prevent forward and rearward movement, a  
9 suture needle-like suture device made of bioabsorbable material  
10 having a hinge-like joint for folding a distal portion at a  
11 precise location to be juxtaposed with a proximal portion for  
12 adjustable locking, and methods of using the suture devices for  
13 joining and approximating tissue, for closing anatomical lumens  
14 and for subcuticular suturing.

15 Some of the advantages of the present invention over the  
16 prior art are that surgeons can easily and quickly utilize the  
17 suture devices during endoscopic surgery to approximate and  
18 join tissue without intricate manipulations and to provide  
19 suture stitches in a short time since the suture devices have  
20 configurations and characteristics to permit manipulation  
21 thereof in a manner similar to suture needles, endoscopic  
22 surgery can be used for additional procedures due to the  
23 reduced time required for suturing coupled with the knotting  
24 function provided by the suture devices, and the suture devices  
25 can replace conventional suturing with a length of suture

SUBSTITUTE SHEET

1 material while providing all of the advantages thereof desired  
2 by surgeons.

3 Other objects and advantages of the present invention will  
4 become apparent from the following description of the preferred  
5 embodiments taken in conjunction with the accompanying  
6 drawings.

7

8

BRIEF DESCRIPTION OF THE DRAWINGS

9 Fig. 1 is a side view of a suture device according to the  
10 present invention.

11 Fig. 1A is a side view of a modification of the suture  
12 device of Fig. 1.

13 Fig. 1B and 1C are broken views of the body member of the  
14 suture device of Fig. 1A.

15 Figs. 1D and 1E are broken views of the body member of the  
16 suture device of Fig. 1.

17 Figs. 2, 3 and 3A are side views showing use of the suture  
18 device of Fig. 1.

19 Fig. 4 is a perspective view of another embodiment of a  
20 suture device according to the present invention.

21 Fig. 5 is a perspective view of the suture device of Fig.  
22 4 in a bent configuration.

23 Fig. 6 is a side view showing use of the suture device of  
24 Fig. 4.

10

1        Fig. 7 is a side view of a further embodiment of a suture  
2 device according to the present invention.

3        Figs. 8 and 9 are side views showing use of the suture  
4 device of Fig. 7.

5        Fig. 10 is a side view of another embodiment of a suture  
6 device according to the present invention.

7        Figs. 10A, 10B and 10C are side views of modifications of  
8 the suture device of Fig. 10.

9        Fig. 11 is an end view of the suture device of Fig. 10.

10       Fig. 12 is a perspective view showing use of the suture  
11 device of Fig. 10.

12       Fig. 13 is a perspective view showing another use of the  
13 suture device of Fig. 10.

14       Fig. 14 is a perspective view showing another use of the  
15 suture device of Fig. 1.

16       Fig. 15 is a side view of an additional embodiment of a  
17 suture device according to the present invention.

18       Fig. 16 is a side view showing use of the suture device  
19 of Fig. 15.

20                    DESCRIPTION OF THE PREFERRED EMBODIMENTS

21        A suture needle-like suture device 20 according to the  
22 present invention is illustrated in Fig. 1 and includes an  
23 elongate, curved body member 22 having a sharp distal end 24  
24 for penetrating tissue in a manner similar to a suture needle  
25 and a bulbous enlarged proximal end 26, the elongate, curved

1 body member 22, having a round shape in cross-section and  
2 gradually tapering from proximal end 26 to sharp distal end 24.  
3 Angled, whisker-like filaments 28 extend from the body member  
4 22 rearwardly toward proximal end 26 and are positioned around  
5 the body member and along the length thereof. The suture  
6 device 20 is made of bioabsorbable material and is intended to  
7 remain in the tissue to be absorbed therein.

8 The use of suture device 20 is illustrated in Figs. 2 and  
9 3 wherein a section of tissue 30 is to be joined to a section  
10 of tissue 32. The tissue can be of any configuration from any  
11 anatomical part or organ of the body; however, the suture  
12 device 20 is particularly useful for various anastomosis or  
13 approximating procedures such as vascular anastomosis, bowel  
14 anastomosis, closure of anatomical or non-anatomical  
15 structures, tuboplasty and skin closure. Due to the smoothly  
16 angled orientation of the whisker-like filaments 28, the suture  
17 device can penetrate through the tissue in only the forward  
18 direction and cannot be moved rearwardly. The sharp distal end  
19 24 is moved to penetrate through tissue section 30 at a  
20 position spaced from the end of the tissue section in a manner  
21 similar to movement of a suture needle and is thereafter moved  
22 to penetrate through tissue section 32 at a position spaced  
23 from the end of tissue section 32. The suture device is  
24 manipulated with a conventional needle holder in a manner  
25 similar to a suture needle and can be easily utilized during

1 endoscopic surgery; and, once the suture device has been  
2 positioned as illustrated in Fig. 2, the distal end is grasped  
3 and pulled thereby approximating the ends of the tissue  
4 sections 30 and 32 as illustrated in Fig. 3, it being noted  
5 that the enlarged bulbous proximal end 26 prevents the suture  
6 device from pulling through tissue section 30 since the  
7 proximal end has a dimension in at least one direction  
8 transverse to the body member greater than the transverse  
9 dimension of the body member. Once the suture device is in the  
10 position illustrated in Fig. 3 with the ends of the tissue  
11 sections approximated, the portion of the suture device  
12 protruding from tissue section 32 is severed as shown at line  
13 34 leaving the suture device in the tissue. The suture device  
14 will remain in position since the angled, whisker-like  
15 filaments will not allow the suture device to move rearwardly  
16 and the enlarged bulbous proximal end 26 will not allow the  
17 suture device to move forwardly. Additionally, by using a  
18 shearing cutting device to sever the protruding distal portion  
19 of the suture device, the cut end can be expanded to form a  
20 flange 35 to further prevent rearward movement of the suture  
21 device. A number of suture devices 20 may be required to  
22 provide a complete suturing procedure; and, for anastomosis or  
23 tuboplasty, as many as four, five or six suture devices may be  
24 used dependent upon the size of the tubular structure and the  
25 thickness of the wall thereof. The suture device will be

1 absorbed in the tissue after joining and healing of the ends  
2 of the tissue sections.

3 By providing body member 22 with an arcuately and smoothly  
4 curving configuration, the suture device 20 can be made of a  
5 rigid bioabsorbable material in that pulling the suture device  
6 through tissue section 32 causes the suture device to  
7 essentially pivot about the proximal end 26 to move tissue  
8 section 32 to abut tissue section 32. It will be appreciated,  
9 however, that suture device 20 can have other configurations  
10 and can be made of bioabsorbable materials of varying  
11 flexibility or rigidity for use with particular anatomical  
12 tissues. For example, suture device 20 can be straight, or  
13 rectilinear, as shown in Fig. 1A at 20a, and made of flexible  
14 bioabsorbable material to allow the body member 22 to bend as  
15 it is drawn through tissue section 32 to approximate the edges  
16 of the tissue sections. The proximal end 26 can have any  
17 desired configuration to prevent forward movement of the suture  
18 device once the suture device has passed through the initial  
19 tissue section; for example, the enlarged proximal end could  
20 have a flat, nail head-type shape, as shown at 26a in Fig. 1A,  
21 or the proximal end could have angled, whisker-like filaments  
22 extending forwardly therefrom toward the sharp distal end. The  
23 body member can have a uniform diameter therealong with a  
24 tapered sharp distal end and can have various cross-sectional  
25 configurations and be either solid or hollow. The whisker-like

1 filaments are preferred to provide the function of permitting  
2 only forward movement of the suture device through the tissue,  
3 or, in other words, preventing reverse movement of the suture  
4 device; however, the body member can carry other means of  
5 permitting only forward movement such as protrusions of various  
6 configurations. By providing the whisker-like filaments along  
7 the length of the body member, the suture device 20 provides  
8 a knotting function similar to tying a knot in a length of  
9 suture material. That is, compression and approximation of the  
10 tissue sections can be variably controlled in accordance with  
11 the tension applied to the suture device as it is pulled  
12 through the tissue by grasping the distal end 24.

13 The suture device 20a has rearwardly angled protrusions  
14 28a having a truncated conical configuration to permit only  
15 forward movement of the suture device, in place of whisker-like  
16 filaments 28, the protrusions being shown in Fig. 1B with a  
17 solid body member 22a and in Fig. 1C with a hollow body member  
18 22b. When the body member is hollow, the interior lumen can  
19 be filled with various pharmacological agents by constructing  
20 the proximal end to be detachable, such as by screw threads or  
21 a friction fit, and microholes 29 extend radially through the  
22 body member to communicate with the lumen and provide passages  
23 for the pharmacological agents to leach out into the suture  
24 site. As previously noted, the use of whisker-like or hair-  
25 like filaments to permit only forward movement of the suture



1 device is preferred in that, as shown in Figs. 1D and 1E, the  
2 filaments lay against body member 22 as the suture device is  
3 moved forwardly to penetrate tissue producing minimal  
4 obstruction to smooth movement. However, any tendency for the  
5 suture device to move rearwardly causes the filaments to  
6 protrude, as shown in Fig. 1, to lock the suture device in the  
7 tissue. The body member 22 in Fig. 1D is solid while the body  
8 member in Fig. 1E is hollow to allow the interior lumen to be  
9 filled with a pharmacological agent for leaching into the  
10 suture site.

11 Another embodiment of a suture device according to the  
12 present invention is illustrated in Fig. 4. The suture needle-  
13 like suture device 36 is integrally formed of bioabsorbable  
14 material and includes a proximal portion 38 having an opening  
15 40 therein defining a bottom edge 42 tapering from a small  
16 width at the proximal end to be progressively wider. The body  
17 of the proximal portion 38 is relatively thick and terminates  
18 at a transversely extending recess 44 which forms a hinge-like  
19 joint defining a precise bending point from which extends a  
20 distal portion 46 tapering to a sharp, suture needle-like point  
21 48 at the distal end of the suture device. A plurality of  
22 tapered barbs 50 extend along the distal portion 46 and, as  
23 illustrated, have truncated, tetrahedral, pyramidal shapes  
24 while other shapes could be provided as will be understood from  
25 the following discussion of the engagement of the barbs with

1 the bottom edge 42 of the opening 40 in the proximal portion  
2 38. For example, whisker-like filaments can protrude from the  
3 distal portion for engaging the proximal portion. The recess  
4 44 allows the suture device 36 to be bent or folded about the  
5 transverse axis thereof, as illustrated in Figs. 5 and 6, such  
6 that the proximal portion 38 and the distal portion 46 can be  
7 juxtaposed. The proximal portion 38 has a concave curved  
8 configuration and the distal portion 46 has a similar curved  
9 configuration such that, when the suture device 36 is bent or  
10 folded on itself at recess 44, the opposing ends of the suture  
11 device extend in opposite directions.

12 In use, the sharp point 48 is moved to penetrate sections  
13 of tissue 52 and 54 to be sutured to approximate the sections  
14 of tissue until recess 44 is positioned adjacent the tissue to  
15 limit further movement of the suture device, it being noted  
16 that the enlarged size of the proximal portion limits  
17 penetration in the tissue. The distal portion 46 is then  
18 folded in a hinge-like manner about the recess 44, and the  
19 sharp distal end 48 is passed through the opening 42 in the  
20 proximal portion such that the suture device 36 now has the  
21 configuration illustrated in Fig. 5. The proximal and distal  
22 portions of the suture device are now forced towards one  
23 another such that the sharp distal end 48 passes through the  
24 opening 42 to protrude from the bottom as shown in Fig. 6. The  
25 distal end 48 can be pulled to adjustably tighten the suture

1 device to provide a knotting function similar to tying a knot  
2 in a length of suture material with the barbs 50 engaging the  
3 bottom edge 42 of the opening 40 to lock the distal portion in  
4 place. The protruding portion of the distal end of the suture  
5 device can be severed as shown at line 56. The suture device  
6 36 will thus hold the tissue in approximated position until the  
7 tissue is joined after which the suture device 36 will be  
8 absorbed in the body.

9 A modification of the suture device of Fig. 4 is  
10 illustrated in Fig. 7 and similar reference numbers with an "a"  
11 added are used to identify similar parts. The suture device  
12 36a is made of flexible bioabsorbable material and includes a  
13 proximal portion 38a having a proximal end 58 around which is  
14 mounted a ring or ring-like member 60 having an opening 42a  
15 therethrough with a conical or tapered inner-surface defining  
16 a locking edge 42a. A transversely extending recess 44a defines  
17 a hinge-like joint at the end of the proximal portion 38a, and  
18 a distal portion 46a extends from recess 44a and tapers to a  
19 sharp, suture needle-like, distal end 48a. Barbs 50a protrude  
20 from distal portion 46a angled in a direction away from distal  
21 end 48a while a plurality of similar barbs 62 protrude from  
22 proximal portion 38a in a direction toward distal end 48a such  
23 that the barbs 50a and 62 are angled toward each other prior  
24 to use of the suture device, as shown in Fig. 7, but are angled  
25 in the same direction when the suture device is bent or folded

1 about recess 44a. The inner surfaces of proximal portion 38a  
2 and distal portion 46a are smooth or longitudinally ribbed or  
3 grooved to abut and/or lock one another when the suture device  
4 is bent at recess 44a.

5 In use, the sharp distal end 48a is moved to penetrate  
6 sections of tissue 52 and 54 to be sutured to approximate the  
7 sections of tissue, and the distal portion 46a is pulled  
8 through the tissue to position recess 44a adjacent the tissue  
9 as shown in Fig. 8. The distal portion is then folded in a  
10 hinge-like manner about the recess 44a such that the proximal  
11 and distal portions are juxtaposed with the sharp distal end  
12 48a received in the opening 42a in ring 60. The ring 60 is  
13 then moved toward the joint (to the left looking at Figs. 8 and  
14 9), it being appreciated that the inner surface of opening 42a  
15 tapers away from the joint such that the ring can move in only  
16 a direction toward the joint. As best shown in Fig. 9, the  
17 ring is moved in a manner similar to a knot during conventional  
18 suturing with a length of suture material until the ring is  
19 positioned as desired; and, once the ring has been properly  
20 positioned, the protruding proximal and distal portions are  
21 severed as indicated at 56a.

22 Suture devices 36 and 36a can have various configurations  
23 and sizes dependent upon the specific tissue to be sutured, it  
24 being important that the suture devices have a well defined  
25 bending or folding joint such that the distal portion can be

1 folded in a hinge-like manner after penetration of the tissue  
2 to be juxtaposed along the proximal portion and engaged or  
3 interlocked with the proximal portion in an adjustable manner  
4 to provide a knotting function similar to tying knots with a  
5 length of suture material. While the distal portion is  
6 adjustably locked in an opening carried by the proximal portion  
7 in suture devices 36 and 36a, other adjustable locking means  
8 could be used as long as operation thereof can be simply  
9 effected to facilitate use. By providing a precise bending  
10 position, use of the suture devices by the surgeon is  
11 facilitated and standardized allowing the surgeon to simply  
12 reproduce the knotting function on a plurality of stitches.  
13 Preferably, the suture devices are made of bioabsorbable  
14 materials having a hardness and rigidity increasing from the  
15 joint toward the proximal and distal ends, and the ring 60 is  
16 made of rigid bioabsorbable material.

17 Another embodiment of a suture needle-like suture device  
18 62 according to the present invention is illustrated in Fig.  
19 10 and includes an elongate body member 64 terminating at a  
20 sharp distal end 66 for penetrating tissue in a manner similar  
21 to a suture needle and at a bulbous enlarged proximal end 68,  
22 the elongate body member having a spiral configuration with the  
23 coils disposed in a single plane and having a round shape in  
24 cross-section. Angled, whisker-like filaments 70 extend from  
25 the body member rearwardly toward proximal end 26 and are

1 positioned around the body member and along the length thereof  
2 such that the suture device 62 can pass through tissue in only  
3 a forward direction. The suture device is made of flexible,  
4 resilient bioabsorbable material such that the suture device  
5 contracts after insertion in tissue to be sutured attempting  
6 to return to its pre-suturing shape; and, accordingly, the  
7 suture device is particularly effective for closing anatomical  
8 lumens and subcuticular suturing. The spiral or coiled  
9 configuration can also circle about a central axis in curves  
10 of conical form, as shown in Figs. 10 and 10D, or cylindrical  
11 form, as shown in Fig. 10B, dependent upon the particular use  
12 of the suture device; and, as noted above with respect to  
13 suture device 20, the proximal end can have any desired  
14 configuration, the cross-section of the body member can vary  
15 and the body member can carry other means of permitting only  
16 forward movement of the suture device. Additionally, the  
17 proximal end 68 can be transposed with the sharp distal end 66  
18 such that the coils become smaller as they approach the distal  
19 end. The suture devices shown in Figs. 10A, 10B and 10C have  
20 expanded pre-suturing states, and the coils in Fig. 10A have  
21 the same diameter while the diameter of the coils in Fig. 10B  
22 increase as they approach the distal end and the diameter of  
23 the coils in Fig. 10C decrease as they approach the distal end.  
24 Parts of the suture devices 62a, 62b and 62c of Figs. 10A, 10B  
25 and 10C, respectively, are given reference number the same as

1 similar parts of suture device 62 with "a", "b", or "c" added,  
2 and the following description of use pertains to suture devices  
3 62, 62a, 62b and 62c.

4 One use of suture device 62 is shown in Fig. 12 wherein  
5 an anatomical lumen 72 in tissue is closed by penetrating the  
6 surrounding tissue with the sharp distal end 66 and rotating  
7 or screwing the suture device into the tissue until proximal  
8 end 68 abuts the tissue. The suture device will be locked in  
9 place since forward movement is prevented by proximal end 68  
10 and rearward movement is prevented by the whisker-like  
11 filaments 70, and the spiral configuration will close the  
12 lumen.

13 Use of the suture device 62 for subcuticular suturing is  
14 shown in Fig. 13 wherein the tissue to be sutured is skin  
15 having an outer layer 74 formed of the epidermis and the  
16 germinal epithelium and a subcutaneous layer of fat 76  
17 primarily formed of collagen. By penetrating the subcutaneous  
18 layer 76 only, and not the outer layer 74, with a series of  
19 suture devices 62, a wound or opening in the skin can be closed  
20 to facilitate healing and minimize scar tissue. The sharp  
21 distal end 66 of the suture device is moved to penetrate the  
22 subcutaneous layer 74 where the first stitch is to be taken,  
23 and the suture device is rotated to cause the suture device to  
24 advance into the subcutaneous layer until the enlarged proximal  
25 end 68 engages the tissue at which point the suture device will

1 be locked in place with the two sides of the wound held in  
2 close engagement for healing while the suture device is  
3 absorbed in the tissue. Thus, suture device 62 can be simply  
4 manipulated by a surgeon to close a wound by subcutaneously  
5 suturing in a time efficient manner.

6 Fig. 14 illustrates use of suture device 20 of Fig. 1 for  
7 subcutaneous suturing, a series of the suture devices 20 being  
8 used in a manner similar to that described above with respect  
9 to suture device 62 with the exception that only a single bite  
10 of tissue is taken with each suture device 20 as compared with  
11 the multiple bites taken with each suture device 62. The  
12 number of coils in the suture device determines the number of  
13 bites taken thereby; and, thus, it will be appreciated that the  
14 number of coils can vary as desired, suture device 20 providing  
15 one bite while suture device 62 provides five bites or  
16 stitches.

17 A modification of the hinge-like foldable suture devices  
18 36 and 36a of Figs. 4 and 7, respectively, is illustrated in  
19 Fig. 15 wherein similar parts are given similar reference  
20 numbers with a " b" added. The suture device 36b of Fig. 15  
21 is integrally formed of bioabsorbable material and includes a  
22 proximal portion 38b having an opening 40b therein, the  
23 proximal portion 38b terminating at a transversely extending  
24 recess 44b forming a hinge-like joint defining a precise  
25 bending point from which extends a distal portion 46b tapering



1 to a sharp, suture needle-like point 48b at the distal end of  
2 the suture device. The opening 40b is formed of a tapering  
3 recess becoming gradually deeper and wider as it approaches the  
4 hinge-like joint. The width of the recess 40b is slightly less  
5 than the corresponding width of the distal portion 46b of the  
6 suture device when the suture device is folded to juxtapose the  
7 proximal and distal portions. The distal portion 46b gradually  
8 tapers to sharp distal point 48b and is faceted. Use of the  
9 suture device 36b is illustrated in Fig. 16 for suturing tissue  
10 52, for example to occlude a tubular body part or organ. The  
11 tissue is penetrated with the sharp distal portion 46b and then  
12 folded at recess 44b to juxtapose the distal and proximal  
13 portions as shown. The distal portion 44b can then be  
14 depressed into the recess opening 40b in an adjustable manner  
15 corresponding to the tissue being sutured, the plastic nature  
16 of the bioabsorbable material holding the distal portion within  
17 the proximal portion.

18 Various bioabsorbable or biodegradable materials can be  
19 used to make the suture devices of the present invention with  
20 the composition determined by the rigidity or flexibility  
21 required. Generally, the bioabsorbable materials are  
22 thermoplastic polymers, such as absorbable polymers and  
23 copolymers of poly-dioxanne, lactide, glycolide and the like.  
24 Polyglycolic acid is disclosed in U.S. Patent Nos. 3,463,158;  
25 3,739,773 and 3,772,420. Suitable polylactic acids are

1 disclosed in U.S. Patent 3,636,956. Examples of absorbable  
2 polyesters are shown in U.S. Patent Nos. 3,225,766 and  
3 3,883,901. Absorbable cellulose glycolic acid ethers are shown  
4 in U.S. Patent No. 2,764,159. Examples of suitable esters of  
5 alpha-cyanoacrylic acid are found in U.S. Patent Nos.  
6 3,527,841, 3,564,078 and 3,759,264.

7 From the above, it will be appreciated that the suture  
8 devices according to the present invention have configurations  
9 to allow the suture devices to be handled or manipulated by  
10 surgeons in a manner similar to conventional suture needles.  
11 That is, the surgeon will grasp the proximal end of the suture  
12 device, for example with a needle holder, and move the suture  
13 needle to penetrate the tissue. The suture devices can be  
14 placed in the tissue in a manner to control and adjust the  
15 tension on the suture device or the compression of the tissue  
16 to produce a knotting function in an efficacious manner easily  
17 accomplished by the surgeon such that suturing and knotting can  
18 be quickly performed during endoscopic surgery.

19 Inasmuch as the present invention is subject to various  
20 modification and changes in detail, the above description of  
21 a preferred embodiment is intended to be exemplary only and not  
22 limiting.

What Is Claimed:

1           1. A suture device for joining bodily tissue comprising  
2           an elongate body member made of bioabsorbable material  
3           having a sharp distal end for penetrating tissue and a proximal  
4           end;

5           means carried on said proximal end for preventing movement  
6           of said proximal end forwardly through the tissue; and

7           means carried on said body member for engaging the tissue  
8           and preventing movement of said member rearwardly through the  
9           bodily tissue.

1           2. A suture device as recited in claim 1 wherein said  
2           means carried on said proximal end includes an enlarged end  
3           having a dimension in at least one direction transverse to said  
4           body member greater than the transverse dimension of said body  
5           member.

1           3. A suture device as recited in claim 2 wherein said  
2           enlarged end has a bulbous configuration.

1           4. A suture device as recited in claim 3 wherein said  
2           means carried on said body member includes protrusion means  
3           extending rearwardly from said body member permitting only  
4           forward movement of said body member through the tissue.

1           5. A suture device as recited in claim 4 wherein said  
2 protrusion means includes whisker-like filaments.

1           6. A suture device as recited in claim 5 wherein said  
2 whisker-like filaments are disposed along substantially the  
3 entire length of said body member.

1           7. A suture device as recited in claim 6 wherein said  
2 body member has a curved configuration such that continuous  
3 forward movement of said member causes bodily tissue sections  
4 to be approximated.

1           8. A suture device as recited in claim 6 wherein said  
2 body member has a coiled configuration.

1           9. A suture device as recited in claim 8 wherein said  
2 coiled configuration is a spiral formed of coils having the  
3 same diameter.

1           10. A suture device as recited in claim 8 wherein said  
2 coiled configuration is a spiral formed of coils having an  
3 increasing diameter as they approach such sharp distal end.

1           11. A suture device as recited in claim 8 wherein said  
2 coiled configuration is a spiral formed of coils having a  
3 decreasing diameter as they approach such sharp distal end.

1           12. A suture device as recited in claim 8 wherein said  
2 coiled configuration is a spiral formed of coils disposed in  
3 a single plane.

1           13. A suture device as recited in claim 1 wherein said  
2 means carried on said body member includes protrusion means  
3 extending rearwardly from said body member permitting only  
4 forward movement of said body member through the tissue.

1           14. A suture device as recited in claim 13 wherein said  
2 protrusion means are whisker-like filaments.

1           15. A suture device as recited in claim 1 wherein said  
2 means carried on said proximal end is disposed along the length  
3 of said body member.

1           16. A suture device as recited in claim 1 wherein said  
2 body member has a curved configuration.

1           17. A suture device as recited in claim 16 wherein said  
2 body member has a coiled configuration.

1           18. A suture device as recited in claim 17 wherein said  
2 coiled configuration is a spiral formed of coils having the  
3 same diameter.

1           19. A suture device as recited in claim 17 wherein said  
2 coiled configuration is a spiral formed of coils having an  
3 increasing diameter as they approach such sharp distal end.

1           20. A suture device as recited in claim 17 wherein said  
2 coiled configuration is a spiral formed of coils having a  
3 decreasing diameter as they approach such sharp distal end.

1           21. A suture device as recited in claim 17 wherein said  
2 coiled configuration is a spiral formed of coils disposed in  
3 a single plane.

1           22. A suture device as recited in claim 1 wherein said  
2 body member has a lumen formed therein for holding a  
3 pharmacological agent and holes therein communicating with said  
4 lumen to allow said pharmacological agent to leach into the  
5 suture site.

1           23. A suture device for joining bodily tissue comprising  
2 a body member having a sharp distal end for penetrating  
3 tissue and a proximal end; and

**SUBSTITUTE SHEET**

4 means carried by said body member for limiting forward  
5 movement of said body member in the tissue and preventing  
6 rearward movement of said body member in the tissue to lock  
7 said suture device in the tissue,

8 said body member and said means carried by said body  
9 member being made of bioabsorbable material.

1 24. A suture device as recited in claim 23 wherein said  
2 means carried by said body member includes joint means defining  
3 a proximal portion of said body member between said joint means  
4 and said proximal end of said body member and defining a distal  
5 portion of said body member between said joint means and said  
6 distal end of said body member, said joint means permitting  
7 said distal portion to be folded to be juxtaposed with said  
8 proximal portion.

1 25. A suture device as recited in claim 24 wherein said  
2 distal portion of said body member includes protrusion means  
3 extending rearwardly toward said joint means.

1 26. A suture device as recited in claim 25 wherein said  
2 proximal portion of said body member includes protrusion means  
3 extending forwardly toward said joint means.

1           27. A suture device as recited in claim 26 and further  
2 comprising a ring-like member disposed on said proximal portion  
3 at a position to receive said distal portion when said distal  
4 portion is juxtaposed with said proximal portion, said ring-  
5 like member being movable along said proximal and distal  
6 portions to adjust tension on said suture device.

1           28. A suture device as recited in claim 24 and further  
2 comprising opening means associated with said proximal portion  
3 for receiving and adjustably locking said distal portion when  
4 said distal portion is juxtaposed with said proximal portion.

1           29. A suture device as recited in claim 28 wherein said  
2 opening means includes a tapered recess disposed in said  
3 proximal portion and said distal portion tapers to said sharp  
4 distal end.

1           30. A suture device as recited in claim 29 wherein said  
2 opening means passes through said proximal portion defining a  
3 locking edge for engaging said distal portion.

1           31. A suture device for joining bodily tissue comprising  
2 a body member having a sharp distal end for penetrating  
3 tissue, a proximal end and joint means disposed between said  
4 distal end and said proximal end defining a distal portion



31

5 between said distal end and said joint means and defining a  
6 proximal portion between said proximal end and said joint  
7 means, said joint means further defining a precise hinge-like  
8 folding location for folding said body member to juxtapose said  
9 distal portion and said proximal portion with said joint means  
10 engaging the tissue, said body member being made of  
11 bioabsorbable material; and

12 means for adjustably engaging said distal portion with  
13 said proximal portion to control tension of said suture device.

1 32. A suture device as recited in claim 31 wherein said  
2 adjustably engaging means includes opening means on said  
3 proximal portion for adjustably receiving said distal portion.

1 33. A suture device as recited in claim 32 wherein said  
2 opening means includes a recess in said proximal portion.

1 34. A suture device as recited in claim 33 wherein said  
2 recess has a tapering configuration and said distal portion has  
3 a tapering configuration to be received and adjustable locked  
4 in said recess when said distal and proximal portions are  
5 juxtaposed.

1 35. A suture device as recited in claim 34 wherein said  
2 body member and said adjustably engaging means are integrally

32

3   formed of bioabsorbable material and said joint means is formed  
4   by a recess extending transversely to the length of said body  
5   member.

1           36. A suture device as recited in claim 32 wherein said  
2   opening means includes an opening passing through said proximal  
3   portion and said distal portion has a configuration to pass  
4   through said opening and be adjustably locked therein when said  
5   distal and proximal portions are juxtaposed.

1           37. A suture device as recited in claim 36 wherein said  
2   body member and said adjustably engaging means are integrally  
3   formed of bioabsorbable material and said joint means is formed  
4   by a recess extending transversely to the length of said body  
5   member.

1           38. A suture device as recited in claim 36 wherein said  
2   distal and proximal portions are curved to cause said distal  
3   and proximal ends to extend toward each other when said distal  
4   and proximal portions are juxtaposed.

1           39. A suture device as recited in claim 32 wherein said  
2   opening means includes a ring-like member having an opening  
3   therethrough receiving said proximal portion and said distal  
4   portion when said distal and proximal portions are juxtaposed,

5 said ring-like member being movable toward said joint means to  
6 adjustably control tension of said suture device.

1 40. A suture needle for joining tissue comprising  
2 an elongate body member having a sharp distal end, a  
3 proximal end and a spiral configuration therebetween forming  
4 a plurality of coils whereby multiple bites of tissue can be  
5 penetrated with said suture needle.

1 41. A suture needle as recited in claim 49 wherein said  
2 spiral configuration is formed of coils having the same  
3 diameter.

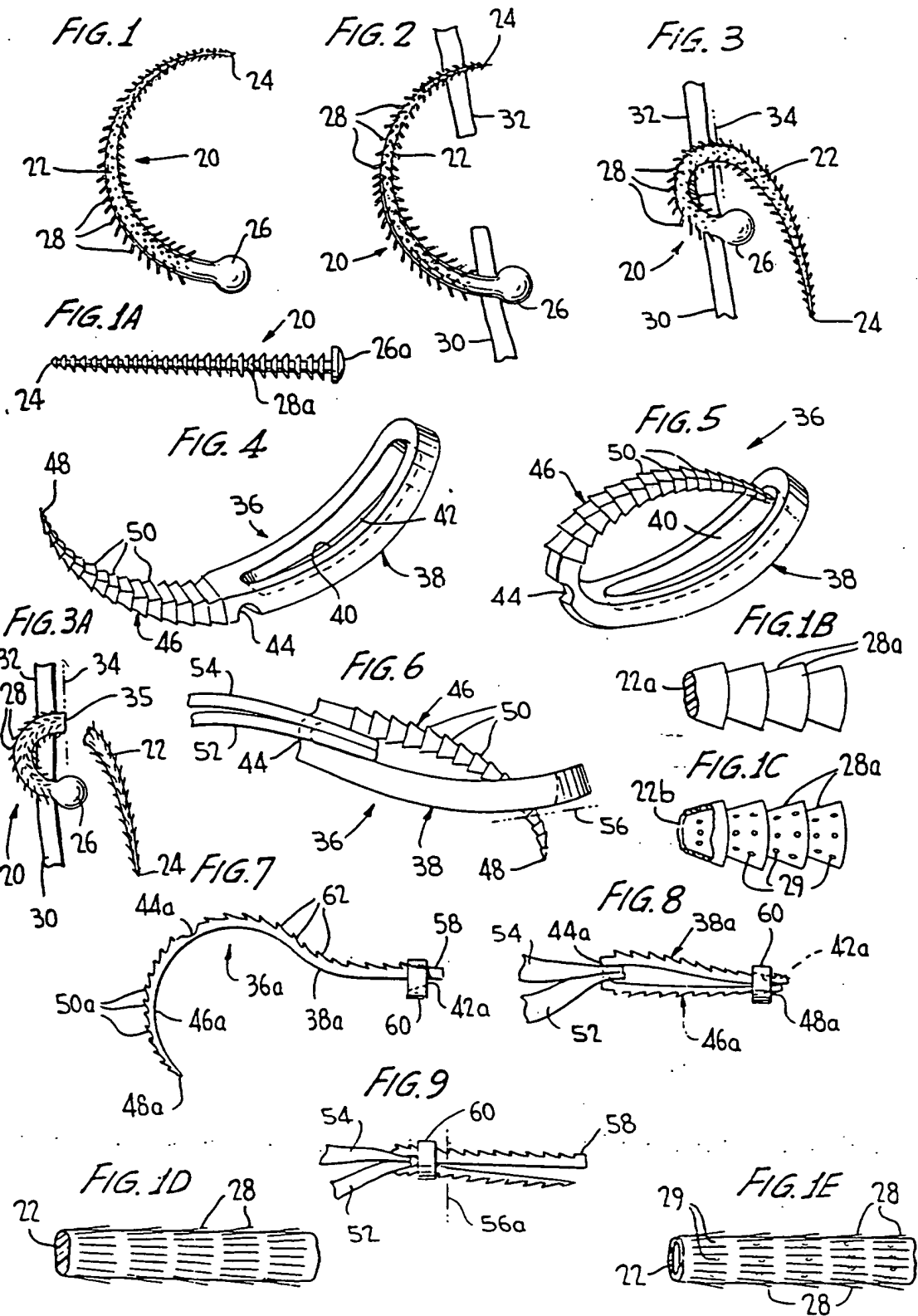
1 42. A suture needle as recited in claim 49 wherein said  
2 spiral configuration is formed of coils having diameters  
3 increasing as they approach said sharp distal end.

1 43. A suture needle as recited in claim 49 wherein said  
2 spiral configuration is formed of coils having diameters  
3 decreasing as they approach said sharp distal end.

1 44. A suture needle as recited in claim 49 wherein said  
2 spiral configuration is formed of coils disposed in a single  
3 plane.

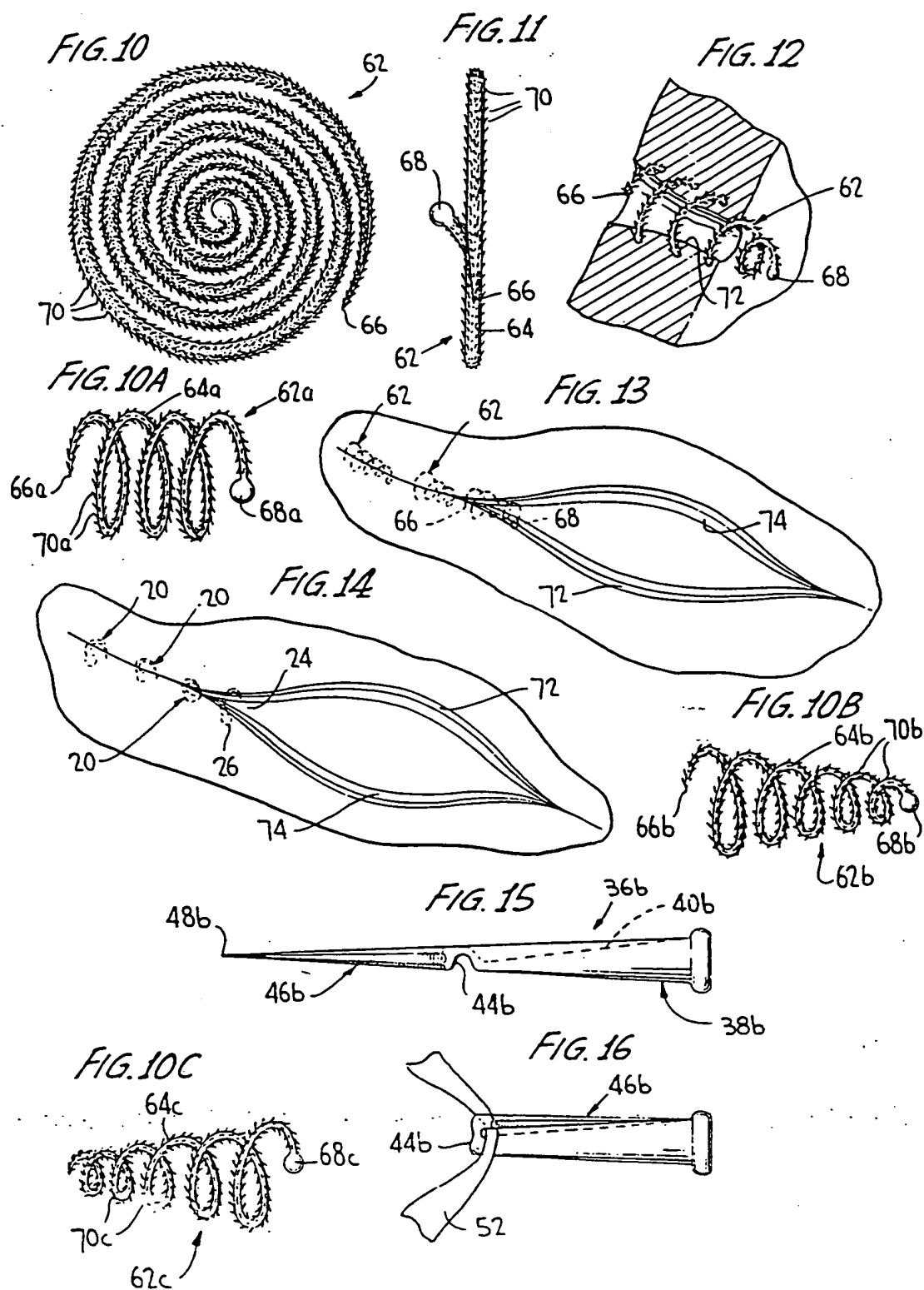
SUBSTITUTE SHEET

1 / 2



SUBSTITUTE SHEET

2 / 2



SUBSTITUTE SHEET

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> : <b>A61B 17/00</b>		(11) International Publication Number: <b>WO 90/14795</b>
A3		(43) International Publication Date: 13 December 1990 (13.12.90)
<p>(21) International Application Number: PCT/US90/02657</p> <p>(22) International Filing Date: 16 May 1990 (16.05.90)</p> <p>(30) Priority data: 352,337 16 May 1989 (16.05.89) US</p> <p>(71)(72) Applicant and Inventor: YOON, InBae [US/US]; 2101 Highland Ridge Drive, Phoenix, MD 21131 (US).</p> <p>(74) Agent: EPSTEIN, Robert, H.; Epstein, Edell &amp; Retzer, 932 Hungerford Drive, Suite 6, Rockville, MD 20850 (US).</p>		<p>(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent)*, DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), SE (European patent).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 24 January 1991 (24.01.91)</p>
<p>(54) Title: SUTURE DEVICES PARTICULARLY USEFUL IN ENDOSCOPIC SURGERY</p> <p>(57) Abstract</p> <p>Suture devices, particularly useful in endoscopic surgery, include a suture device made of bioabsorbable material having an elongate body member with a sharp distal end for penetrating tissue and means for locking the suture device in tissue to prevent forward and rearward movement and a suture device made of bioabsorbable material having a hinge-like joint for folding a distal portion at a precise location to be juxtaposed with a proximal portion for adjustable locking. Methods of using the suture devices for joining tissue sections, such as in tuboplasty, for closing anatomical lumens and for subcuticular suturing.</p>		

\* See back of page

## DESIGNATIONS OF "DE"

Until further notice, any designation of "DE" in any international application whose international filing date is prior to October 3, 1990, shall have effect in the territory of the Federal Republic of Germany with the exception of the territory of the former German Democratic Republic.

### FOR THE PURPOSES OF INFORMATION ONLY

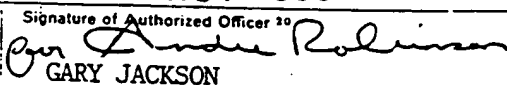
Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MC	Monaco
AU	Australia	FI	Finland	MG	Madagascar
BB	Barbados	FR	France	ML	Mali
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GR	Greece	NL	Netherlands
BJ	Benin	HU	Hungary	NO	Norway
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	SD	Sudan
CF	Central African Republic	KP	Democratic People's Republic of Korea	SE	Sweden
CG	Congo	KR	Republic of Korea	SN	Senegal
CH	Switzerland	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
DE	Germany, Federal Republic of	LU	Luxembourg	TC	Togo
DK	Denmark			US	United States of America

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US90/02657

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>1</sup> According to International Patent Classification (IPC) or to both National Classification and IPC IPC(5): A61B 17/00 US Cl.: 606/232, 228, 223		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>4</sup>		
Classification System	Classification Symbols	
US	606/213, 216, 221-225, 228, 220	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched <sup>4</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>11</sup>		
Category <sup>8</sup>	Citation of Document, <sup>12</sup> with indication, where appropriate, of the relevant passages <sup>13</sup>	Relevant to Claim No. <sup>14</sup>
X	US, A, 3,570,497 LEMOLE 16 March 1971 See column 3, lines 45-72	1,23
Y,P	US, A, 4,832,026 JONES 23 May 1989 See column 1, lines 54-68 and column 2, lines 1-4	1-7,13,16
Y	US, A, 4,006,747 KRONENTHAL 08 February 1977 See column 1, lines <del>56-64</del>	1-7,13,16
A	US, A, 2,413,142 JONES 24 December 1946 See column 4, lines 29-55	1-7,13,16
A	US, A, 3,166,072 SULLIVAN 19 January 1965 See column 1, lines 8-36	1-7,13,16
Y	US, A, 3,123,077 ALCAMO 03 MARCH 1964 See column 1, lines 5-31	1-7,13,16
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><sup>15</sup> Special categories of cited documents: <sup>16</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"I" document member of the same patent family</p> </div> </div>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search <sup>1</sup>		Date of Mailing of this International Search Report <sup>2</sup>
18 OCTOBER 1990		26 NOV 1990
International Searching Authority <sup>1</sup>		Signature of Authorized Officer <sup>10</sup>
ISA/US		 GARY JACKSON



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☒ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**